PATENT

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/Kurt L. Grossman/ — July 15, 2008
Kurt L. Grossman, Reg. No. 29,799 — Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
***Ex parte* Pope et al.**
Appeal No. _________

Serial No.: 10/700,738
Filed: November 4, 2003
Art Unit: 3767
Examiner: Elizabeth MacNeill
Appellants: Brian Pope and Zhan Liu
For: **SYRINGE PUMP RAPID OCCLUSION DETECTION SYSTEM**
Atty. Docket No.: MDX-297
Confirmation No.: 4966

Cincinnati, OH 45202 — July 15, 2008

Mail Stop APPEAL BRIEF – PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

APPEAL BRIEF

This Appeal Brief is in furtherance of Appellants' Notice of Appeal filed May 27, 2008, appealing the decision of the Examiner in the Final Official Action mailed on February 25, 2008 rejecting claims 1-3, 5-36, and 46-80 (all pending claims).

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I. REAL PARTY IN INTEREST

The real party in interest is Smiths Medical ASD, Inc., a corporation of the State of Delaware, a subsidiary of Smiths Group plc, a corporation of England, UK. Medex, Inc., formerly a corporation of the State of Ohio and the Assignee of record was merged into Smiths Medical ASD, Inc. in August of 2006.

II. <u>RELATED APPEALS AND INTERFERENCES</u>

There are no related appeals or interferences known to the Appellants or the Appellants' legal representative that will directly affect, or be directly affected by, or have a bearing on the decision of the Board in the present appeal.

III. STATUS OF CLAIMS

Claims 1-3, 5-36 and 46-80 are presently pending, stand rejected, and are the subject of this appeal. A copy of the presently pending claims is included in the Claims Appendix.

IV. STATUS OF AMENDMENTS

There were no amendments made to the claims after the Final Official Action mailed February 25, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claims 1, 13, 46, 55, 74, and 78 are independent claims, and the rest of claims 2, 3, 5-12, 14-36, 47-54, 56-73, 75-77, and 79-80 are dependent claims. For the purposes of this appeal, focus will be on the independent claims 1, 13, 46, 55, 74, and 78 as well as dependent claims 3, 15, and 57. The citations below are to the published version of the patent application, namely, Pope et al. U.S. Patent Application Publication No. 2005/0096593.

Independent Claim 1

Appellants' independent claim 1 is directed towards a method of automatically detecting an occlusion in a fluid line 22 of a syringe pump 10. *See* FIGS. 1-3 and paragraph [0025], as well as paragraph [0035] and paragraph [0085]. The syringe pump 10 includes a housing 14 adapted to support a syringe 13 containing a plunger 16 moveable inside the syringe 13 by pushing an end of a plunger 16 with a pusher 17 to expel fluid from an outlet of the syringe 13 into a fluid line 22 connected to the outlet and configured to carry the fluid under pressure to a patient 24. *See* FIG. 1 and paragraphs [0025]-[0028]. The method comprises mounting the syringe 13 onto the housing14 with the plunger 16 end extended, coupling the pusher 17 to the end of the plunger 16, and initiating a pumping sequence to cause the fluid to flow into the fluid line 22. *See* paragraphs [0025]-[0026] as well as FIG. 3 block 202 and paragraphs [0036]-[0042]. The method further comprises using a sensor 33 to determine a first instantaneous force value F1 indicative of force in the fluid line 22 at instantaneous time T1 during the pumping sequence and a second instantaneous force value F2 indicative of force in the fluid line 22 at instantaneous time T2 during the pumping sequence. *See* FIG. 3 blocks 204 through 206 and paragraphs [0043]-[0045]. The method provides an indication of the occlusion if a slope calculated by dividing a difference between the second instantaneous force value F2 and the first

instantaneous force value F1 by a difference between instantaneous time T1 and instantaneous time T2 departs from an expected slope relationship. *See* FIG. 3 blocks 209 through 217 and paragraphs [0048]-[0051].

<u>Dependent Claim 3</u>

Appellants' claim 3 depends from claim 1 and adds that the method of claim 1 further comprises determining a steady state condition. *See* FIG. 3 block 208 and paragraph [0047], as well as FIG. 6 blocks 402-246 and paragraphs [0059]-[0067].

<u>Independent Claim 13</u>

Appellants' independent claim 13 is directed towards a method of automatically detecting an occlusion in a fluid line 22 of a medical pumping system 10. *See* FIGS. 1-3 and paragraph [0025], as well as paragraph [0035] and paragraph [0085]. The fluid line 22 is configured to carry fluid under pressure between a fluid source and a patient 24. *See* FIG. 1 and paragraphs [0025]-[0028]. The method comprises determining a first instantaneous force value F1 indicative of force in the fluid line 22 at instantaneous time T1 during a pumping sequence and determining a second instantaneous force value F2 indicative of force in the fluid line 22 at instantaneous time T2 during the pumping sequence. *See* FIG. 3 blocks 204 through 206 and paragraphs [0043]-[0045]. The method further comprises providing an indication of the occlusion if a slope calculated by dividing a difference between the second instantaneous force value F2 and the first instantaneous force value F1 by a difference between instantaneous time T1 and instantaneous time T2 departs from an expected slope relationship. *See* FIG. 3 blocks 209 through 217 and paragraphs [0048]-[0051]

Dependent Claim 15

Appellants' claim 15 depends from claim 13 and adds that the method of claim 13 further comprises determining a steady state condition. *See* FIG. 3 block 208 and paragraph [0047], as well as FIG. 6 blocks 402-246 and paragraphs [0059]-[0067].

Independent Claim 46

Appellants' independent claim 46 is directed towards a syringe pumping system 10. *See* FIG. 1 and paragraph [0025]. The syringe pumping system 10 includes a syringe 13 configured to contain fluid and an outlet. *See* FIG. 1 and paragraph [0025]. A housing 14 is adapted to support the syringe 13, and a plunger 16 having an end is configured to move within the syringe 13. *See* FIG. 1 and paragraphs [0025]-[0026]. A pusher 17 is adapted to attach to, and push, the end of the plunger 16 so as to cause the fluid to exit out of the outlet of the syringe 13. *See* FIG. 1 and paragraphs [0025]-[0028]. A fluid line 22 is connected to the outlet of the syringe 13 and configured to carry the fluid under force to a patient 24. *See* FIG. 1 and paragraph [0025]. A sensor 33 determines at least a first and second instantaneous force values F1 and F2 indicative of the force between the syringe and the patient taken at instantaneous times T1 and T2, respectively. *See* FIG. 2 and paragraph [0030], as well as FIG. 3 blocks 204 through 206 and paragraphs [0043]-[0045], FIG. 6 block 404 and paragraph [0062], as well as FIG. 7 block 489 and paragraph [0068]. A processor 31 in communication with the pusher 17 is configured to execute program code that determines if a slope calculated by dividing a difference between the second instantaneous force value F2 and the first instantaneous force value F1 by a difference between instantaneous time T1 and instantaneous time T2 departs from an expected slope relationship. *See* FIG. 2 and paragraphs [0030]-[0032], FIG. 3 block 210 and paragraph [0049],

FIG. 6 block 412 and paragraph [0066], as well as FIG. 7 block 492 and paragraph [0071]-[0072].

Independent Claim 55

Appellants' independent claim 55 is directed towards a pumping system 10. *See* FIG. 1 and paragraph [0025], as well as paragraph [0035] and paragraph [0085]. The pumping system 10 includes a fluid source and a fluid line 22 configured to carry fluid under pressure between the fluid source and a patient 24. *See* FIG. 1 and paragraphs [0025]-[0028]. A sensor 33 determines at least a first and a second instantaneous force value F1 and F2 indicative of the force between the fluid source and the patient taken at instantaneous times T1 and T2, respectively. *See* FIG. 2 and paragraph [0030], FIG. 3 blocks 204 through 206 and paragraphs [0043]-[0045], FIG. 6 block 404 and paragraph [0062], as well as FIG. 7 block 489 and paragraph [0068]. A pump is configured to generate a force between the fluid source and the patient 24. *See* FIG. 1 and paragraphs [0025]-[0028], as well as paragraph [0035] and paragraphs [0084]-[0085]. A processor 31 is in communication with the pump and configured to execute program code that determines if a slope calculated by dividing a difference between the second instantaneous force value F2 and the first instantaneous force value F1 by a difference between instantaneous time T1 and instantaneous time T2 departs from an expected slope relationship. *See* FIG. 2 and paragraphs [0030]-[0032], FIG. 3 block 210 and paragraph [0049], FIG. 6 block 412 and paragraph [0066], as well as FIG. 7 block 492 and paragraph [0071]-[0072].

Dependent Claim 57

Appellants' claim 57 depends from claim 55 and adds that the program code initiates determining a steady state condition. *See* FIG. 3 block 208 and paragraph [0047], as well as FIG. 6 blocks 402-246 and paragraphs [0059]-[0067].

Independent Claim 74

Appellants' independent claim 74 is very much like independent claim 55, but with the processor 31 being configured to execute program code that initiates altering delivery of the fluid in response to determining that the slope deviates from an expected value. *See* FIG. 2 and paragraphs [0030]-[0032] as well as FIG. 8 and paragraphs [0074]-[0084]. Thus, like independent claim 55, independent claim 74 is directed towards a pumping system 10. *See* FIG. 1 and paragraph [0025], as well as paragraph [0035] and paragraphs [0084]-[0085]. The pumping system 10 includes a fluid source and a fluid line 22 configured to carry fluid under pressure between the fluid source and a patient 24. *See* FIG. 1 and paragraphs [0025]-[0028]. A sensor 33 determines at least a first and a second instantaneous force value F1 and F2 indicative of the force between the fluid source and the patient 24 taken at instantaneous times T1 and T2, respectively. *See* FIG. 2 and paragraph [0030], FIG. 3 blocks 204 through 206 and paragraphs [0043]-[0045], FIG. 6 block 404 and paragraph [0062], FIG. 7 block 489 and paragraph [0068], as well as FIG. 8 block 504 and paragraph [0076] and paragraphs [0084]-[0085]. A pump is configured to generate a force between the fluid source and the patient 24. *See* FIG. 1 and paragraphs [0025]-[0028], as well as paragraphs [0084]-[0085]. A processor 31 is in communication with the pump and configured to execute program code that initiates altering delivery of the fluid in response to determining that a slope calculated by dividing a difference between the second instantaneous force value F2 and the first instantaneous force value F1 by a

difference between instantaneous time T1 and instantaneous time T2 deviates from an expected slope relationship. *See* FIG. 2 and paragraphs [0030]-[0032], as well as FIG. 8 blocks 506 through 520, paragraphs [0077]-[0083], and paragraphs [0084]-[0087].

Independent Claim 78

Appellants' independent claim 78 is very much like independent claim 46, but with the processor 31 being configured to execute program code that initiates altering delivery of the fluid in response to determining that the slope deviates from an expected value. *See* FIG. 2 and paragraphs [0030]-[0032] as well as FIG. 8 and paragraphs [0074]-[0083] and paragraphs [0084]-[0085]. Thus, like independent claim 46, independent claim 74 is directed towards a syringe pumping system 10. *See* FIG. 1 and paragraph [0025]. The syringe pumping system 10 includes a syringe 13 configured to contain fluid and an outlet. *See* FIG. 1 and paragraph [0025]. A housing 14 is adapted to support the syringe 13, and a plunger 16 having an end is configured to move within the syringe 13. *See* FIG. 1 and paragraphs [0025]-[0026]. A pusher 17 is adapted to attach to, and push, the end of the plunger 16 so as to cause the fluid to exit out of the outlet of the syringe 13. *See* FIG. 1 and paragraphs [0025]-[0028]. A fluid line 22 is connected to the outlet of the syringe 13 and configured to carry the fluid under force to a patient 24. *See* FIG. 1 and paragraph [0025]. A sensor 33 determines at least a first and a second instantaneous force value F1 and F2 indicative of the force between the syringe 13 and the patient 24 taken at instantaneous times T1 and T2, respectively. *See* FIG. 2 and paragraph [0030], FIG. 3 blocks 204 through 206 and paragraphs [0043]-[0045], FIG. 6 block 404 and paragraph [0062], FIG. 7 block 489 and paragraph [0068], as well as FIG. 8 block 504 and paragraph [0076] and paragraphs [0084]-[0085]. A processor 31 in communication with the pusher 17 is configured to execute program code that initiates altering delivery of the fluid in response to determining that a

slope calculated by dividing a difference between the second instantaneous force value F2 and the first instantaneous force value F2 by a difference between instantaneous time T1 and instantaneous time T2 deviates from an expected value. *See* FIG. 2 and paragraphs [0030]-[0032], as well as FIG. 8 blocks 506 through 520, paragraphs [0077]-[0083], and paragraphs [0084]-[0087]

It should be noted that, as none of the claims recite any means plus function or step plus function elements, no identification of such elements is required pursuant to 37 CFR § 41.37 (c)(1)(v).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. The rejection of claims 1-3, 5-31, 46-67, 72-74, and 78 under 35 U.S.C. 103(a) as allegedly unpatentable over Jhuboo et al. U.S. Patent No. 5,501,665 (Jhuboo).

2. The rejection of claims 32, 34, 36, 68, 70, 76, 77, and 80 under 35 U.S.C. 103(a) as allegedly unpatentable over Jhuboo in view of Tribe et al. U.S. Patent Publication No. 2003/0205587 (Tribe).

3. The rejections of claims 33, 35, 69, 71, 75, and 79 under 35 U.S.C. 103(a) as allegedly unpatentable over Jhuboo in view of Moberg et al. U.S. Patent No. 6,485,465 (Moberg).

VII. ARGUMENTS

A. The Cited Art Neither Discloses Nor Renders Obvious the Claimed Invention

This appeal is taken from the Final Official Action of February 25, 2008 (Final Official Action). Claims 1-3, 5-31, 46-67, 72-74, and 78 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,501,665 to Jhuboo et al. (Jhuboo). Claims 32, 34, 36, 68, 70, 76, 77, and 80 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Jhuboo in further view of U.S. Patent Publication No. 2003/0205587 to Tribe et al. (Tribe). Claims 33, 35, 69, 71, 75, and 79 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Jhuboo in further view of U.S. Patent No. 6,485,465 to Moberg et al. (Moberg).

Appellant's arguments in rebuttal to the Examiner's rejections are presented below, starting with the relevant independent claims and followed by a discussion of selected dependent claims. For purposes of this Appeal Brief, focus will primarily be on the obviousness rejections of the independent claims 1, 13, 46, 55, 74, and 78, with specific mention of dependent claims 3, 15, and 55, which are rejected only under Jhuboo. The omission of a discussion with respect to any particular claim, however, should not be interpreted as an acquiescence as to the merits of the Examiner's rejection of the claim, particularly with respect to claims reciting features that are addressed in connection with the rejection applied to other claims pending in the appeal.

With regard to all rejections, Examiner concedes that Jhuboo does not disclose the claimed invention. Instead, Examiner persists in using egregiously faulty reasoning to attribute non-existent teachings to Jhuboo in order to wrongly support her obviousness rejections.

1. Overview

Jhuboo is related generally to detecting an obstruction in a perfusion line in a particular manner following a particular procedure. Jhuboo begins by measuring the average pressure (P) over three consecutive periods of time (Δt): $P_{\Delta t1}$, $P_{\Delta t2}$, and $P_{\Delta t3}$. Jhuboo, col. 4, line 55 to col. 5, line 1. Calculated changes in average pressure over those intervals (e.g., col. 5, lines 17-19 and lines 23-25) are compared to an experimental gradient multiplied by the interval being analyzed (e.g., col. 5, lines 17-39, and FIG. 8 steps 130 to 134). If the changes in the average pressure over the intervals are greater than the experimental gradient, Jhuboo determines that an obstruction has occurred and generates an alarm signal. Jhuboo, col. 5, lines 20-23. In sum, Jhuboo determines obstructions in a perfusion line by analyzing average pressures over three consecutive time intervals and comparing them to a predetermined gradient. Jhuboo, FIG. 8 and col. 5, line 20 to col. 6, line 30.

Standing in stark contrast to the Jhuboo's analysis of average pressures, Appellants' claimed invention relates generally to detecting occlusions in a fluid line by determining first and second instantaneous force values F1 and F2, respectively, in a fluid at first and second instantaneous times T1 and T2, respectively. A slope is calculated that corresponds to the difference between F2 and F1 divided by the difference between T1 and T2. Claims 1 and 13 are method claims that provide an indication if the calculated slope departs from an expected slope relationship. Claims 46 and 55 are claims directed towards a syringe pumping system and a pumping system, respectively, in which a processor determines if the calculated slope departs from an expected slope relationship. Claims 74 and 78 are claims directed towards a pumping system and a syringe pumping system, respectively, in which a processor initiates altering delivery of the fluid in response to determining that the slope deviates from an expected value.

Thus, the claimed invention measures two instantaneous force values to calculate the slope of the line between the force values over time and analyzes the calculated slope to determine if there is an occlusion and/or action required. Examiner fails to cite anything in Jhuboo that satisfies the limitations of the present claims, and admits that Jhuboo fails to disclose all the limitations of the present claims. Jhuboo is directed towards detecting an obstruction in a perfusion line with average pressure samples and most certainly does not disclose detecting occlusions in a fluid line by determining first and second instantaneous force values F1 and F2, respectively, in a fluid at first and second instantaneous times T1 and T2, respectively, calculating a slope based thereon, and determining if that slope departs from an expected slope relationship. In alleging that the present claims are obvious, Examiner attempts to transform Jhuboo into something it is not and allege that it would be obvious to set Δt (the period of time in which to measure average pressure) to zero, or a value approaching zero. In setting Δt to zero or a value approaching zero, however, Examiner creates a fictitious reference contradicted by the plain teachings of Jhuboo and that would render Jhuboo inoperable, if not fatal.

Jhuboo's occlusion detection system ostensibly worked for its intended purposes, and there neither was, nor is there, a need or basis to look at altering the disclosure thereof as Examiner has suggested. Examiner's alterations do nothing more than make a blatantly incorrect assumption that Jhuboo would operate at instantaneous times without any support from the specification of Jhuboo. In this manner, Examiner clearly uses the claimed invention as a blueprint to engage in *ex post* reasoning for the rejections, a clear violation of law. *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1729, 82 USPQ2D 1385, 1397 (2007) (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 36 (1966)) ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant on *ex post*

reasoning."). Thus, as discussed in greater detail below, Jhuboo does not at all render obvious the claimed invention. Accordingly, the rejections are clear error and must be reversed.

As previously discussed, focus herein will be on the independent claims with specific mention of dependent claims where it is deemed necessary. As explained below, the rejections of the independent claims must be reversed. As a matter of law, the rejections of the dependent claims necessarily must also be reversed. *See, e.g., Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987) (dependent claims patentable if independent claims are patentable over the art).

2. Examiner's Unwarranted Assumptions Regarding the Independent Claims

A *prima facie* case of obviousness requires that Examiner establish that the differences between a claimed invention and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." *KSR*, 127 S. Ct. at 1734 (citing 35 U.S.C. §103(a)). A *prima facie* showing of obviousness is satisfied if there is an apparent reason to modify the prior art reference flowing from either the reference, the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved, and the results are expected. *Id.* at 1740; *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Appellants submit that the position that Examiner has taken can only be the result of improper hindsight reconstruction based on the claimed invention as well as a fanciful construction of Jhuboo that is fatally flawed. Most certainly, it is not the stuff of which a prima facie case of obviousness is made.

Claims 1, 13, 46, 55, 74 and 78 disclose calculating a slope by determining instantaneous force values at discrete times while Jhuboo is limited to utilizing the average of force over time to calculate a gradient. In operation, the claimed invention is particularly distinct from Jhuboo

because it utilizes differences between the instantaneous force values and discrete times rather than averaging force values over an interval. However, Examiner's primary allegation can be summarized to say that although Jhuboo does not disclose using "instantaneous force values," Jhuboo can be modified to calculate force values as Δt equal zero, or as the limit of Δt approaches zero.

a. <u>Jhuboo's Failures During Normal Operations</u>

Examiner fails to acknowledge that the operation of the claimed invention and Jhuboo are fundamentally different such that there is no basis for the 35 U.S.C. § 103(a) rejections. Examiner's rejections are clear error showing a misunderstanding of both the purpose of Jhuboo and the reality of mathematics. Quite simply, there is a significant disconnect between the present claims, how Examiner characterizes the present claims, and the disclosure of Jhuboo. Further explanation will be made clear by way of the following illustrations.

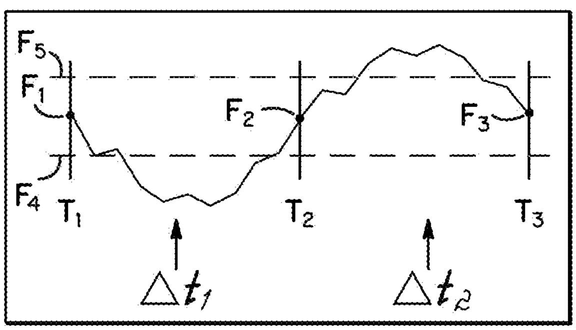

FIG. 1

FIG. 1 is an illustration of forces on a fluid over time which will be used as an example to illustrate possible implementations of the claimed invention and Jhuboo (no concession is made that the present claims are limited in this fashion, but this example is used to help explain the fallacy of Examiner's position). In this example of the claimed invention, the forces F_1, F_2, and F_3 may be measured at the three distinct instantaneous times T_1, T_2, and T_3, respectively, and the

slopes calculated of the line from F_1 to F_2 (line F_1F_2), the line from F_2 to F_3 (line F_2F_3), or the line from F1 to F3 (line F_1F_3). Significantly, the slopes of all of lines F_1F_2, F_2F_3, and F_1F_3 are similar in magnitude and, in FIG. 1, the slopes of all the lines are approximately horizontal. Thus, when the slope of any one of the three lines is not sufficient to indicate an occlusion, the claimed invention does not detect an occlusion, avoiding useless noise that could otherwise skew results.

With respect to Jhuboo, the average forces during the intervals of Δt_1 and Δt_2 are measured. The values for the average forces during the intervals Δt_1 and Δt_2 are shown illustratively as dashed lines F_4 and F_5, respectively. To detect an obstruction, Jhuboo determines the difference between F_4 and $F_{5,}$ then divides that by the difference between intervals Δt_1 and Δt_2 (mathematically, the difference between the intervals being: $(T_3\text{-}T_2)\text{-}(T_2\text{-}T_1)$). With reference to FIG. 1, Jhuboo might determine that an obstruction has occurred because of a gradient set up by F_4,F_5, Δt_1 and Δt_2, when in fact Jhuboo was simply averaging noise. The claimed invention would avoid this improper result by only analyzing the difference between instantaneous values of F_1, F_2, and/or F_3 at instantaneous times T_1, T_2, and/or T_3, respectively.

b. <u>**Jhuboo's Failures at Instantaneous and Near Instantaneous Force Values**</u>

Examiner sweeps these operational differences aside on the baseless assumption that Δt could approach zero in order to support the argument that it would have been obvious to one skilled in the art to use instantaneous force values in Jhuboo. But Examiner concedes that Jhuboo nowhere suggests using an instantaneous force value at a discrete time to determine a gradient. Indeed, Jhuboo would not work using instantaneous force values. So, Examiner engages in a bit of mathematical alchemy to reach a conclusion that not only breaks several of the fundamental rules of mathematics, but is also directly at odds with the disclosure of Jhuboo.

In particular, while Jhuboo always uses a time span of Δt, Examiner concludes that one with knowledge of calculus would also realize that using the limit as Δt approaches zero is also appropriate to determine instantaneous force values.

While actually being at zero would give instantaneous force values, to the extent Δt is not zero, Examiner is wrong. A Δt that is greater than zero will necessarily involve taking an average, even if Δt becomes so small that the force values at either end are the same. But that is not the same as taking a force measurement at a specific time and using that measurement. Instead, Examiner ultimately creates a complicated averaging system over infinitesimally small time intervals, which is not the claimed invention. Examiner has no choice but to create the fiction that Δt approaching zero is no different than Δt set to zero. By way of the following illustrations this fiction will be further explained.

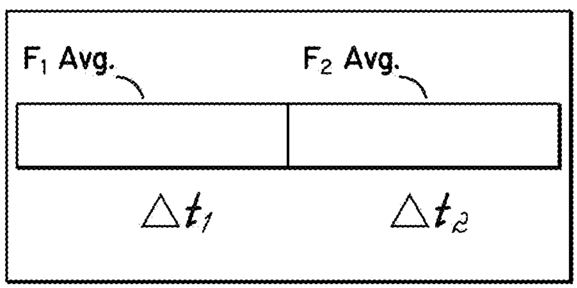

FIG. 2

FIG. 2 is a diagrammatic illustration of the consecutive measurements taken by Jhuboo with large intervals of Δt_1 and Δt_2 during which to find average force values, F_1 Avg. and F_2 Avg., respectively. As previously discussed, Jhuboo determines a gradient from the difference between F_1 Avg. and F_2 Avg. divided by the difference between Δt_1 and Δt_2.

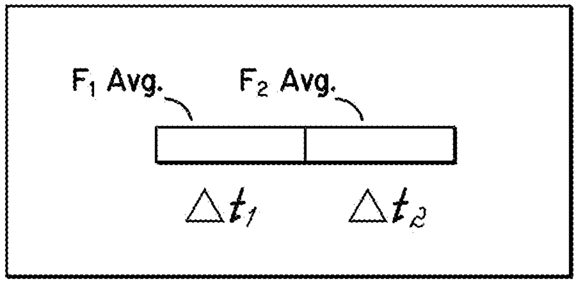

FIG. 3

FIG. 3 is a diagrammatic illustration of the consecutive measurements taken by Jhuboo with smaller intervals of Δt_1 and Δt_2 during which to find average force values, F_1 Avg. and F_2 Avg., respectively. Although Jhuboo does disclose that Δt can be small (e.g., col. 5 lines 48-50), this is only in relation to the exemplary value of one minute (e.g., col. 6 lines 7-9). Interestingly, by moving towards the direction of Δt having a value of zero (or a value approaching zero), Jhuboo fails mathematically and functionally.

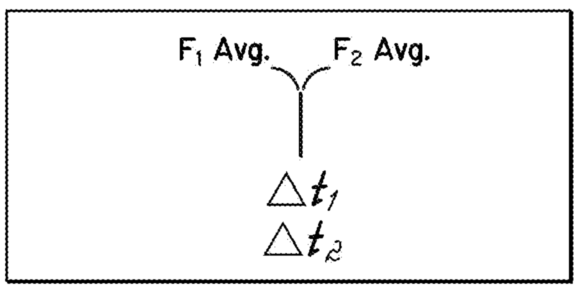

FIG. 4

FIG. 4 is an illustration of the effect that Δt having a value of zero (or a value approaching zero using Examiner's hypothesis) will have on the intervals Δt_1 and Δt_2 and average force values F_1 Avg. and F_2 Avg., respectively, in Jhuboo. To that end, the consecutive intervals used by Jhuboo, Δt_1 and Δt_2, also must collapse toward zero, such that only one value will be obtained for both intervals. Thus, by constricting Δt to zero or a value approaching zero, the value of F_1 Avg. will the same as F_2 Avg. Any calculation of the difference between F_1 Avg.

and F_2 Avg. will, in that scenario, also have to approach or be zero, rendering the Jhuboo system non-functional.

Furthermore, Jhuboo uses Δt as a denominator ($S=\Delta P/\Delta t$, at col. 5 line 5). Hence, were Δt_1 and Δt_2 set to zero, the result would be a gradient of infinity, again rendering Jhuboo useless. Additionally, were Δt set to a value approaching zero, Δt_1 and Δt_2 would still approach zero. The result would still be a gradient approaching infinity, again rendering Jhuboo useless. A person skilled in the art would not have considered it obvious to make gradient comparisons with values that approach infinity as such gradient comparisons would be futile.

As illustrated by the foregoing, the claimed invention cannot be rendered obvious by Jhuboo. Despite Examiner's allegations, setting Δt to a value of zero or a value approaching zero does nothing more than render Jhuboo useless. Thus, it is amply demonstrated that Jhuboo would lead a person of ordinary skill in the art to follow a different path than setting Δt equal to or approaching zero. *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant."). Additionally, it is amply demonstrated that Examiner's proposed modification of Jhuboo would render it inoperable and/or change the principle of operation of the invention. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354, 60USPQ2d 1001, 1010 (a reference may teach away from a use when the use would render the result inoperable); *In re Gordon*, 733 F.3d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (a reference teaches away from proposed modifications that render the disclosed invention inoperable for its intended purpose); *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (if the proposed modification or combination of the prior art would change the principle of

operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious). Even *KSR* indicates that when the prior art teaches away from a combination, that combination is more likely to be nonobvious. *KSR*, 127 S. Ct. at 1739-1740.

With this in mind, it seems painfully clear that Examiner has simply shoehorned Appellants' invention into the disclosure of Jhuboo with the magic incantation of *KSR*. The *KSR* decision lends no support to Examiner's allegation that Jhuboo would "perform equally well using an instantaneous force value," as *KSR* nowhere suggests that obviousness can be established by ignoring mathematical reality and operational reality. As previously indicated, *KSR* cautions against the type of *ex post* reasoning Examiner applied here. *KSR*, 127 S. Ct. at 1729.

c. <u>Examiner's Allegations of Obviousness are Without Merit</u>

Examiner has most recently alleged that Jhuboo "discloses that prior art devices use instantaneous times/forces to detect occlusions." Presumably, Examiner refers to Jhuboo at col. 1, line 29, which refers to the process of the prior art described in col. 1, lines 16-27 as one that uses "instantaneous pressure."[1] However, that discussion has nothing to do with the present invention. In fact, Examiner has misapplied Jhuboo's discussion of the prior art to sustain the rejections. Jhuboo describes the prior art as follows:

> "The simplest process involves monitoring the pressure in the perfusion line at regular time intervals. When the pressure exceeds a predetermined level, an alarm signal is generated. To minimize false alarms, the pressure at which the alarm is triggered is fixed at a level much higher than the normal line pressure. The use of this process requires a relatively long time interval to detect an obstruction, since the pressure in the line must reach the alarm level before an obstruction is detected."

[1] Appellants stress "presumably," as Examiner has again failed to provide more than a conclusory statement without any support in Jhuboo for this assertion.

Thus, Jhuboo merely describes prior art pressure monitoring systems that read a pressure at discrete time intervals and trigger an alarm when that pressure exceeds a fixed level. Jhuboo's description of the prior art still fails to disclose or suggest determining any gradients or slopes, as well as determining whether those gradients or slopes depart from an expected slope relationship and/or deviate from an expected value, which is the focus of the present invention. Thus, the prior art as described by Jhuboo still fails to disclose or suggest all the limitations of the claimed invention.

However, Examiner attempts to trivialize differences between Jhuboo and the claimed invention to allege that one would recognize that "Jhuboo's method 'being characterized by the fact that it comprises steps consisting of selecting a gradient constant; measuring an initial pressure in the perfusion line; measuring a second pressure in the perfusion line after a time interval; subtracting the first pressure from the second pressure to obtain a first pressure difference; comparing the first pressure difference to the gradient constant; and generating a signal if the first pressure difference to the gradient constant' (Col. 1 at line 35) would apply to instantaneous forces as well as average forces." (Internal citations omitted.) Examiner's characterization of Jhuboo is clearly in error. Jhuboo must be read in light of its specification, which indicates that <u>any</u> reference to pressure is a reference to an average pressure. Jhuboo, col. 4, line 55 to col. 5, line 1 (describing "pressure measurement" as Pi, Pi+1, and Pi +2 mean pressures); Jhuboo, col. 5, l ine 2 to col. 6, line 62 (consistently referring to determining the mean pressures over the time interval Δt). Thus, Jhuboo still fails to disclose determining instantaneous forces F1 and F2 at instantaneous times T1 and T2, respectively, the determination of the slope with F1, F2, T1 and T2, and the determination of the departure from an expected slope relationship or deviation from an expected value. Again, Jhuboo cannot be divorced from

its disclosure, which indicates that Jhuboo determines obstructions in a perfusion line by analyzing average pressures over consecutive time intervals and comparing them to a predetermined gradient.

d. Jhuboo Teaches Away from the Claimed Invention

Nowhere does *KSR* suggest that obviousness can be established by extracting from a reference a concept that is at odds with the reference. Yet, this is precisely what Examiner has continued to do throughout the prosecution of the claimed invention. In particular, as Examiner has dismissed mathematics by setting Δt to zero (or a value approaching zero), Examiner has further dismissed, without comment, the effect that this would have on Δt optimization and the relationship of Δt to noise and the perfusion rate as set forth in Jhuboo. Consideration of the full disclosure of Jhuboo yields a result contrary to Examiner's position, revealing that Examiner's proposed modifications to Jhuboo would render Jhuboo inoperable, if not fatal, as well as destroy the intended purpose of Jhuboo and/or change the principle of operation of the invention as further explored below.

i) Examiner Ignores Jhuboo's Δt Optimization

Jhuboo discloses a procedure to "optimize" Δt as illustrated in FIGS. 9 and 10. In order to allege that it would have been obvious for Δt to approach or equal zero, Examiner wholly ignores the plain teachings of Jhuboo to create an alternate reality where Jhuboo can coherently disclose two contradictory teachings at once. For example, although Examiner alleges that Jhuboo teaches that Δt can be set to zero or a value approaching zero, Jhuboo's optimization procedure establishes the opposite of what Examiner asserts, namely that Δt should never be set to approach or equal. FIGS. 9 and 10 of Jhuboo both show a determination of whether $|P_{i+1} - P_i| > K_1 S_0 \Delta t_i$ (e.g., see calculations in col. 6). However, setting Δt to approach or equal zero

prevents any optimization of Δt and destroys the illustrative procedure disclosed in FIGS. 9 and 10. Thus, with one hand Examiner alleges that it would have been obvious for a person having ordinary skill in the art to set Δt to a value approaching or equal zero, while waiving away the fact that Jhuboo is inoperable as Δt approaches or equals zero with the other hand. For example, when Δt approaches or equals zero, Jhuboo would calculate future values of Δt as similarly approaching or equaling zero. Because Δt would approach or equal zero, the values of $K_i S_0 \Delta t_i$ would always be infinitesimally small or zero. Thus, the absolute value of $P_{i+1} - P_i$ would always be greater than the infinitesimally small or zero value of $K_1 S_0 \Delta t_i$, resulting in a feedback loop that destroys the intended purpose of Jhuboo's Δt optimization. Examiner has provided no reason why a person having ordinary skill in the art would desire to render optimizations of Δt meaningless. Without meaningful values of Δt at the preferred and exemplified value of one minute (e.g., col. 6, lines 7-9), Jhuboo is rendered inoperable.

ii) <u>Examiner Ignores Real World Noise</u>

In rejecting the claimed invention, Examiner further ignores real world noise conditions that affect modern electronics by alleging that Jhuboo can operate with Δt set to approach or equal zero. Any electronic device, system, or apparatus must take into account electrical noise that is produced by the electronics of that apparatus or its surroundings. Jhuboo discloses that if the system is experiencing noise, Δt <u>must</u> be large to compensate for the interference. Jhuboo, col. 5 lines 47-48. But by asserting that Δt can be a value of zero or a value approaching zero, Examiner engages in the unrealistic fiction that all electronics operate in a perfect system. A person having ordinary skill in the art (and operating in the real world) would most certainly realize that Jhuboo requires that Δt be larger than either a value of zero or a value approaching zero for adequate noise compensation because each component of an electronic device, system,

or apparatus creates noise that must be adressed. Incredulously, Examiner continues to allege that setting Δt to approach or equal zero would be apparent to one having ordinary skill in the art. One having ordinary skill in the art would instead recognize that altering Jhuboo to include a Δt that approaches or equals zero is contrary to the facts of Jhuboo and the reality of electronics.

iii) <u>Examiner Ignores Ballooning Perfusion Rates</u>

Were Jhuboo's Δt allowed to approach or equal zero, it is likely that Jhuboo's device would fail, and might even result in death to a patient. Certainly, this is not a desirable result. Jhuboo expresses an inverse dependency between Δt and the perfusion rate. Thus, the perfusion rate in Jhuboo is set by a user (e.g., col. 5 lines 54-55) with Δt having an inversely proportional relationship to that rate (e.g., col. 5 lines 53-54). When Δt is set to a value, such as at 1 μSec (which is certainly still well above a value approaching zero), the perfusion rate would have to escalate to a value of 1000 L per hour (see calculations in col. 5 lines 53-55 and the exemplary value of Δt=1 minute at col. 6 lines 7-9). Correspondingly, for Δt to be set to a value of zero, the perfusion rate would seem to balloon incredibly to a value of infinity. That these perfusion rates could have devastating results on a patient is not addressed by Examiner. Examiner nonetheless blithely assumes, without any evidentiary support, that there is nothing to having Δt be a value of zero or a value approaching zero in Jhuboo. Examiner is tragically wrong and engaging in sheer fancy.

3. <u>Examiner's Unwarranted Assumptions Regarding Dependent Claims</u>

Dependent claims 3 and 15 further limit the methods of claims 1 and 13 to determining a steady state condition. Similarly, dependent claim 57 further limits the program code of the system of claim 55 to initiate determining a steady state condition. While the independent claims from which these claims depend are patentable over Jhuboo for the reasons discussed above, the

additional determination of a steady state condition provides a separate basis for a determination of non-obvious for these dependent claims.

A steady state is a state at which initial conditions of an infusion will have less impact on detecting occlusions. In particular, a steady state condition is a time after which elevated startup slopes associated with a pre-steady state timeframe normally level off. See Published Application at paragraph [0065] (describing a definition of a steady state condition) as well as paragraphs [0059] through [0067] (describing detection of the steady state condition). Examiner rejects the limitations of dependent claims 3, 15, and 57 by simply stating "(gradient constant)" without any further substantive discussion. Presumably, Examiner is referring to the "predetermined gradient" value, "S_0,"described in Jhuboo. However, S_0 cannot be considered the same as a "steady state condition" because S_0 is a numeric value "deduced experimentally by measuring the gradients of the pressure/time curve with obstructions found in the fluid line and different flow rates" that is programmed into the device of Jhuboo for use at any time that device is turned on. Jhuboo, col. 5 lines 31-33. It is ludicrous for Examiner to assert that a constant (S_0) is the same as determining a steady state condition of a live system without a more thorough explanation to which the Appellants' can respond. In fact, "to conclude otherwise can only be the result of information gleaned from Appellant's own patent application," which is impermissible hindsight reconstruction and fatal to a 35 U.S.C. § 103 rejection. *W.L. Gore & Associates, Inc., v. Garlock Inc.*, 721 F.2d 1540; MPEP §2145. Thus, for at least these further reasons, the rejections of dependent claims 3, 15, and 57 are clearly in error and must be reversed in any event.

B. CONCLUSION

For at least the reasons discussed above, Appellants respectfully submit that the rejections of claims 1-3, 5-36 and 46-80 are clearly in error and must be reversed. As such, Appellants respectfully request that the Board reverse Examiner's rejections. The Appeal Brief fee is submitted concurrently herewith. If any other charges or credits are necessary to complete this communication, please apply them to Deposit Account 23-3000.

Respectfully submitted,

WOOD, HERRON & EVANS, L.L.P.

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VII. CLAIMS APPENDIX: CLAIMS ON APPEAL

(S/N 10/700,738)

1. (Previously Presented) A method of automatically detecting an occlusion in a fluid line of a syringe pump, the syringe pump including a housing adapted to support a syringe containing a plunger moveable inside the syringe by pushing an end of a plunger with a pusher to expel fluid from an outlet of the syringe into a fluid line connected to the outlet and configured to carry the fluid under pressure to a patient, the method comprising:

mounting the syringe onto the housing with the plunger end extended;

coupling the pusher to the end of the plunger;

initiating a pumping sequence to cause the fluid to flow into the fluid line;

during the pumping sequence, using a sensor to determine a first instantaneous force value F1 indicative of force in the fluid line at instantaneous time T1;

during the pumping sequence, determining a second instantaneous force value F2 indicative of force in the fluid line at instantaneous time T2; and

providing an indication of the occlusion if a slope calculated by dividing a difference between the second instantaneous force value F2 and the first instantaneous force value F1 by a difference between instantaneous time T1 and instantaneous time T2 departs from an expected slope relationship.

2. (Previously Presented) The method of automatically detecting an occlusion of claim 1, further comprising providing no occlusion indication where the calculated slope does not depart from the expected slope relationship.

3. (Original) The method of automatically detecting an occlusion of claim 1, further comprising determining a steady state condition.

4. (Canceled)

5. (Previously Presented) The method of automatically detecting an occlusion of claim 1, further comprising determining a time window defining at least one of time T1 and time T2.

6. (Previously Presented) The method of automatically detecting an occlusion of claim 1, wherein providing the indication of the occlusion further includes determining the expected slope relationship.

7. (Previously Presented) The method of automatically detecting an occlusion of claim 1, wherein providing the indication of the occlusion further includes determining a trial slope using at least one of the first and second instantaneous force values.

8. (Original) The method of automatically detecting an occlusion of claim 1, wherein providing the indication of the occlusion further includes determining an occlusion slope.

9. (Previously Presented) The method of automatically detecting an occlusion of claim 1, wherein providing the indication of the occlusion further includes comparing the expected slope relationship to the calculated slope.

10. (Original) The method of automatically detecting an occlusion of claim 1, wherein providing the indication of the occlusion further includes comparing an occlusion slope to a trial slope.

11. (Previously Presented) The method of automatically detecting an occlusion of claim 1, further comprising shifting a time window to obtain an additional instantaneous force value.

12. (Original) The method of automatically detecting an occlusion of claim 1, further comprising canceling the indication of the occlusion in response to a comparison between a trial slope and a cancellation slope.

13. (Previously Presented) A method of automatically detecting an occlusion in a fluid line of a medical pumping system, the fluid line being configured to carry fluid under pressure between a fluid source and a patient, the method comprising:

during a pumping sequence, determining a first instantaneous force value F1 indicative of force in the fluid line at instantaneous time T1;

during the pumping sequence, determining a second instantaneous force value F2 indicative of force in the fluid line at instantaneous time T2; and

providing an indication of the occlusion if a slope calculated by dividing a difference between the second instantaneous force value F2 and the first instantaneous force value F1 by a difference between instantaneous time T1 and instantaneous time T2 departs from an expected slope relationship.

14. (Previously Presented) The method of automatically detecting an occlusion of claim 13, further comprising providing no occlusion indication where the calculated slope does not depart from the expected slope relationship.

15. (Original) The method of automatically detecting an occlusion of claim 13, further comprising determining a steady state condition.

16. (Original) The method of automatically detecting an occlusion of claim 15, wherein determining the steady state condition further includes determining a steady state startup time period.

17. (Original) The method of automatically detecting an occlusion of claim 16, wherein determining the steady state condition further includes determining a startup time limit.

18. (Original) The method of automatically detecting an occlusion of claim 16, wherein determining the steady state condition further includes determining a startup fluid volume.

19. (Previously Presented) The method of automatically detecting an occlusion of claim 13, wherein determining at least one of the first and second instantaneous force values further includes using a sensor.

20. (Previously Presented) The method of automatically detecting an occlusion of claim 13, wherein determining at least one of the first and second instantaneous force values further includes determining a count indicative of the at least one of the first and second instantaneous force values.

21. (Original) The method of automatically detecting an occlusion of claim 20, further comprising adjusting at least one of time T1 and time T2 to avoid fractioning the count.

22. (Original) The method of automatically detecting an occlusion of claim 20, further comprising using a transducer to generate the count.

23. (Previously Presented) The method of automatically detecting an occlusion of claim 13, further comprising determining a time window defining at least one of time T1 and time T2.

24. (Original) The method of automatically detecting an occlusion of claim 13, wherein providing the indication of the occlusion further includes generating an alarm.

25. (Previously Presented) The method of automatically detecting an occlusion of claim 13, wherein providing the indication of the occlusion further includes determining the expected slope relationship.

26. (Previously Presented) The method of automatically detecting an occlusion of claim 13, wherein providing the indication of the occlusion further includes determining a trial slope using at least one of the first and second instantaneous force values.

27. (Original) The method of automatically detecting an occlusion of claim 13, wherein providing the indication of the occlusion further includes determining an occlusion slope.

28. (Previously Presented) The method of automatically detecting an occlusion of claim 13, wherein providing the indication of the occlusion further includes comparing the expected slope relationship to the calculated slope.

29. (Original) The method of automatically detecting an occlusion of claim 13, wherein providing the indication of the occlusion further includes comparing an occlusion slope to a trial slope.

30. (Previously Presented) The method of automatically detecting an occlusion of claim 13, further comprising shifting a time window to obtain an additional instantaneous force value.

31. (Original) The method of automatically detecting an occlusion of claim 13, further comprising canceling the indication of the occlusion in response to a comparison between a trial slope and a cancellation slope.

32. (Previously Presented) The method of automatically detecting an occlusion of claim 13, wherein determining the first instantaneous force value further includes altering delivery of the fluid.

33. (Previously Presented) The method of automatically detecting an occlusion of claim 13, wherein determining the first instantaneous force value further

includes altering delivery of the fluid in response to comparing the first instantaneous force value to a bolus occlusion limit.

34. (Previously Presented) The method of automatically detecting an occlusion of claim 33, wherein determining the first instantaneous force value further includes resuming delivery of the fluid after a delay time.

35. (Previously Presented) The method of automatically detecting an occlusion of claim 33, wherein determining the first instantaneous force value further includes resuming delivery of the fluid in response to comparing the first instantaneous force value to a bolus occlusion limit.

36. (Original) The method of automatically detecting an occlusion of claim 13, wherein providing the indication of the occlusion further includes initiating a remedial action.

37-45. (Canceled)

46. (Previously Presented) A syringe pumping system, comprising:

a syringe configured to contain fluid and including an outlet;

a housing adapted to support the syringe;

a plunger having an end and configured to move within the syringe;

a pusher adapted to attach to and push the end of the plunger so as to cause the fluid to exit out of the outlet of syringe;

a fluid line connected to the outlet of the syringe and configured to carry the fluid under force to a patient;

a sensor for determining at least first and second instantaneous force values F1 and F2 indicative of the force between the syringe and the patient taken at instantaneous times T1 and T2, respectively; and

a processor in communication with the pusher, the processor being configured to execute program code that determines if a slope calculated by dividing a difference between the second instantaneous force value F2 and the first instantaneous force value F1 by a difference between instantaneous time T1 and instantaneous time T2 departs from an expected slope relationship.

47. (Previously Presented) The syringe pumping system of claim 46, wherein the program code initiates providing an indication of an occlusion if the calculated slope departs from the expected slope relationship.

48. (Previously Presented) The syringe pumping system of claim 46, wherein the program code initiates determining a time window defining at least one of time T1 and time T2.

49. (Previously Presented) The syringe pumping system of claim 46, wherein the program code initiates determining the expected slope relationship.

50. (Previously Presented) The syringe pumping system of claim 46, wherein the expected slope relationship includes an occlusion slope.

51. (Previously Presented) The syringe pumping system of claim 46, wherein the program code initiates comparing the expected slope relationship to the calculated slope.

52. (Original) The syringe pumping system of claim 46, wherein the program code initiates comparing an occlusion slope to a trial slope.

53. (Previously Presented) The syringe pumping system of claim 46, wherein the program code initiates determining a third instantaneous force value indicative of a force between the fluid source and the patient taken at times T2 and T3, respectively.

54. (Previously Presented) The syringe pumping system of claim 46, wherein the program code initiates determining a third instantaneous force value indicative of a force between the fluid source and the patient taken at times T1 and T3, wherein T3 is subsequent to T2.

55. (Previously Presented) A pumping system, comprising:

a fluid source;

a fluid line configured to carry fluid under pressure between the fluid source and a patient;

a sensor for determining at least first and second instantaneous force values F1 and F2 indicative of the force between the fluid source and the patient taken at instantaneous times T1 and T2, respectively;

a pump configured to generate a force between the fluid source and the patient; and

a processor in communication with the pump, the processor being configured to execute program code that determines if a slope calculated by dividing a difference between the second instantaneous force value F2 and the first instantaneous force value F1 by a difference between instantaneous time T1 and instantaneous time T2 departs from an expected slope relationship.

56. (Previously Presented) The pumping system of claim 55, wherein the program code initiates providing an indication of an occlusion if the calculated slope departs from the expected slope relationship.

57. (Original) The pumping system of claim 55, wherein the program code initiates determining a steady state condition.

58. (Previously Presented) The pumping system of claim 55, wherein the program code initiates determining a count indicative of the at least one of the first and second instantaneous force values.

59. (Previously Presented) The pumping system of claim 55, further comprising a transducer configured to generate a count from at least one of the first and second instantaneous force values.

60. (Previously Presented) The pumping system of claim 55, wherein the program code initiates determining a time window defining at least one of time T1 and time T2.

61. (Previously Presented) The pumping system of claim 55, wherein the program code initiates determining the expected slope relationship.

62. (Previously Presented) The pumping system of claim 55, wherein a relationship between the first and second force instantaneous values includes a trial slope.

63. (Previously Presented) The pumping system of claim 55, wherein the expected slope relationship includes an occlusion slope.

64. (Previously Presented) The pumping system of claim 55, wherein the program code initiates comparing the expected slope relationship to the calculated slope.

65. (Original) The pumping system of claim 55, wherein the program code initiates comparing an occlusion slope to a trial slope.

66. (Previously Presented) The pumping system of claim 55, wherein the program code initiates shifting a time window to obtain an additional instantaneous force value.

67. (Original) The pumping system of claim 55, wherein the program code initiates canceling the indication of the occlusion in response to a comparison between a trial slope and a cancellation slope.

68. (Original) The pumping system of claim 55, wherein the program code initiates altering delivery of the fluid.

69. (Previously Presented) The pumping system of claim 55, wherein the program code initiates altering delivery of the fluid in response to comparing the first instantaneous force value to a bolus occlusion limit.

70. (Original) The pumping system of claim 69, wherein the program code initiates resuming delivery of the fluid after a delay time.

71. (Previously Presented) The pumping system of claim 69, wherein the program code initiates resuming delivery of the fluid in response to comparing the first instantaneous force value to a bolus occlusion limit.

72. (Previously Presented) The pumping system of claim 55, wherein the program code initiates determining a third instantaneous force value indicative of a force between the fluid source and the patient taken at times T2 and T3, respectively.

73. (Previously Presented) The pumping system of claim 55, wherein the program code initiates determining a third instantaneous force value indicative of a force between the fluid source and the patient taken at times T1 and T3, wherein T3 is subsequent to T2.

74. (Previously Presented) A pumping system, comprising:

a fluid source;

a fluid line configured to carry fluid under force between the fluid source and a patient;

a sensor for determining at least first and second instantaneous force values F1 and F2 indicative of the force between the fluid source and the patient taken at instantaneous times T1 and T2, respectively;

a pump configured to generate the force between the fluid source and the patient; and

a processor in communication with the pump, the processor being configured to execute program code that initiates altering delivery of the fluid in response to determining that a slope calculated by dividing a difference between the second instantaneous force value F2 and the first instantaneous force value F1 by a difference between instantaneous time T1 and instantaneous time T2 deviates from an expected value.

75. (Original) The pumping system of claim 74, wherein the program code initiates determining if a bolus infusion is being delivered.

76. (Original) The pumping system of claim 74, wherein the program code initiates resuming the delivery of the fluid after a delay period.

77. (Original) The pumping system of claim 74, wherein the program code initiates resuming the delivery of the fluid at a reduced infusion rate.

78. (Previously Presented) A syringe pumping system, comprising:

a syringe configured to contain fluid and including an outlet;

a housing adapted to support the syringe;

a plunger having an end and configured to move within the syringe;

a pusher adapted to attach to and push the end of the plunger so as to cause the fluid to exit out of the outlet of syringe;

a fluid line connected to the outlet of the syringe and configured to carry the fluid under force to a patient;

a sensor for determining at least first and second instantaneous force values F1 and F2 indicative of the force between the fluid source and the patient taken at instantaneous times T1 and T2, respectively; and

a processor in communication with the pusher, the processor being configured to execute program code that initiates altering delivery of the fluid in response to determining that a slope calculated by dividing a difference between the second instantaneous force value F2 and the first instantaneous force value F1 by a difference between instantaneous time T1 and instantaneous time T2 deviates from an expected value.

79. (Original) The pumping system of claim 78, wherein the program code initiates determining if a bolus infusion is being delivered.

80. (Original) The pumping system of claim 78, wherein the program code initiates resuming the delivery of the fluid after a delay period.

81. - 85. (Canceled)

IX. EVIDENCE APPENDIX

(S/N 10/700,738)

None.

X. RELATED PROCEEDINGS APPENDIX

(S/N 10/700,738)

None.